

CY 2014 CDER New Molecular Entity (NME) Drug & Original BLA Calendar Year Approvals

As of December 31, 2014

This report reflects the data shown as it is identified in the database.

Selection Criteria:

User Response: Start Date: 1/1/2014 End Date: 12/31/2014

Sort Order: Approval Date

New Molecular Entity Application (NME) Approvals:

APPLICATION NUMBER	PROPRIETARY NAME	ESTABLISHED NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
NDA 202293	FARXIGA	DAPAGLIFLOZIN	ASTRAZENECA AB	S	1/8/2014	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 205677	HETLIOZ	TASIMELTEON	VANDA PHARMACEUTICALS INC	P,O	1/31/2014	FOR NON-24 HOUR SLEEP-WAKE DISORDER IN BLIND PATIENTS WITHOUT LIGHT PERCEPTION
NDA 203202	NORTHERA	DROXIDOPA	CHELSEA THERAPEUTICS INC	P,O	2/18/2014	FOR THE TREATMENT OF ORTHOSTATIC DIZZINESS, LIGHTEADEDNESS, OR THE "FEELING THAT YOU ARE ABOUT TO BLACK OUT" IN ADULT PATIENTS WITH SYMPTOMATIC NEUROGENIC ORTHOSTATIC HYPOTENSION CAUSED BY PRIMARY AUTONOMIC FAILURE (PARKINSON'S DISEASE, MULTIPLE SYSTEM ATROPHY, AND PURE AUTONOMIC FAILURE), DOPAMINE BETA-HYDROXYLASE DEFICIENCY, AND NON-DIABETIC AUTONOMIC NEUROPATHY
NDA 204677	NEURACEQ	FLORBETABEN	PIRAMAL IMAGING SA	S	3/19/2014	FOR POSITRON EMISSION TOMOGRAPHY (PET) IMAGING OF THE BRAIN TO ESTIMATE B AMYLOID NEURITIC PLAQUE DENSITY IN ADULT PATIENTS WITH COGNITIVE IMPAIRMENT WHO ARE BEING EVALUATED FOR ALZHEIMER'S DISEASE OR OTHER CAUSES OF COGNITIVE DECLINE
NDA 204684	IMPAVIDO	MILTEFOSINE	PALADIN THERAPEUTICS INC	P,O	3/19/2014	FOR TREATMENT OF VISCERAL LEISHMANIASIS DUE TO LEISHMANIA DONOVANI, CUTANEOUS LEISHMANIASIS DUE TO LEISHMANIA BRAZILIENSIS, LEISHMANIA GUYANENSIS, AND LEISHMANIA PANAMENSIS AND MUCOSAL LEISHMANIASIS DUE TO LEISHMANIA BRAZILIENSIS
NDA 205437	OTEZLA	APREMILAST	CELGENE CORP	S	3/21/2014	FOR THE TREATMENT OF ADULT PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

NDA 205755	ZYKADIA	CERITINIB	NOVARTIS PHARMACEUTICALS CORP	P,O	4/29/2014	FOR THE TREATMENT OF PATIENTS WITH ANAPLASTIC LYMPHOMA KINASE (ALK)-POSITIVE METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC) WHO HAVE PROGRESSED ON OR ARE INTOLERANT TO CRIZOTINIB
NDA 204886	ZONTIVITY	VORAPAXAR	MERCK SHARP AND DOHME CORP	S	5/8/2014	FOR THE REDUCTION OF THROMBOTIC CARDIOVASCULAR EVENTS IN PATIENTS WITH A HISTORY OF MYOCARDIAL INFARCTION (MI) OR WITH PERIPHERAL ARTERIAL DISEASE (PAD)
NDA 021883	DALVANCE	DALBAVANCIN	DURATA THERAPEUTICS INTERNATIONAL BV	P	5/23/2014	FOR THE TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS
NDA 203567	JUBLIA	EFINACONAZOLE	DOW PHARMACEUTICAL SCIENCES	S	6/6/2014	FOR THE TOPICAL TREATMENT OF ONYCHOMYCOSIS OF THE TOENAILS DUE TO TRICHOPHYTON RUBRUM AND TRICHOPHYTON MENTAGROPHYTES
NDA 205435	SIVEXTRO	TEDIZOLID PHOSPHATE	CUBIST PHARMACEUTICALS INC	P	6/20/2014	FOR THE TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS
NDA 206256	BELEODAQ	BELINOSTAT	SPECTRUM PHARMACEUTICALS INC	P,O	7/3/2014	FOR THE TREATMENT OF PATIENTS WITH RELAPSED OR REFRACTORY PERIPHERAL T-CELL LYMPHOMA
NDA 204427	KERYDIN	TAVABOROLE	ANACOR PHARMACEUTICALS INC	S	7/7/2014	FOR THE TOPICAL TREATMENT OF ONYCHOMYCOSIS OF THE TOENAILS DUE TO TRICHOPHYTON RUBRUM OR TRICHOPHYTON MENTAGROPHYTES
NDA 205858	ZYDELIG	IDELALISIB	GILEAD SCIENCES INC	S,O	7/23/2014	FOR RELAPSED FOLLICULAR B-CELL NON-HODGKIN LYMPHOMA (FL) IN PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES AND RELAPSED SMALL LYMPHOCYTIC LYMPHOMA (SLL) IN PATIENTS WHO HAVE RECEIVED AT LEAST TWO PRIOR SYSTEMIC THERAPIES
NDA 203108	STRIVERDI RESPIMAT	OLODATEROL	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	7/31/2014	CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD), INCLUDING CHRONIC BRONCHITIS AND/OR EMPHYSEMA
NDA 204629	JARDIANCE	EMPAGLIFLOZIN	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	S	8/1/2014	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS
NDA 206334	ORBACTIV	ORITAVANCIN DIPHOSPHATE	THE MEDICINES CO	P	8/6/2014	FOR THE TREATMENT OF ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTIONS (ABSSSI)
NDA 204569	BELSOMRA	SUVOREXANT MK-4305	MERCK SHARP AND DOHME CORP	S	8/13/2014	FOR THE TREATMENT OF INSOMNIA IN ADULTS

NDA 205494	CERDELGA	ELIGLUSTAT	GENZYME CORP	P,O	8/19/2014	FOR THE LONG-TERM TREATMENT OF ADULT PATIENTS WITH GAUCHER DISEASE TYPE 1 WHO ARE CYP2D6 EXTENSIVE METABOLIZERS (EMS), INTERMEDIATE METABOLIZERS (IMS), OR POOR METABOLIZERS (PMS)
NDA 204760	MOVANTIK	NALOXEGOL	ASTRAZENECA PHARMACEUTICALS LP	S	9/16/2014	FOR THE TREATMENT OF OPIOID-INDUCED CONSTIPATION (OIC) IN ADULT PATIENTS WITH CHRONIC NON-CANCER PAIN
NDA 203684	LUMASON	SULFUR HEXAFLUORIDE LIPID-TYPE A MICROSPHERES	BRACCO DIAGNOSTICS INC	S	10/10/2014	FOR USE IN PATIENTS WITH SUBOPTIMAL ECHOCARDIOGRAMS TO OPACIFY THE LEFT VENTRICULAR CHAMBER AND TO IMPROVE THE DELINEATION OF THE LEFT VENTRICULAR ENDOCARDIAL BORDER
NDA 205718	AKYNZEO	NETUPITANT AND PALONOSETRON	HELSINN HEALTHCARE SA	S	10/10/2014	FOR PREVENTION OF ACUTE AND DELAYED NAUSEA AND VOMITING ASSOCIATED WITH INITIAL AND REPEAT COURSES OF CANCER CHEMOTHERAPY, INCLUDING, BUT NOT LIMITED TO, HIGHLY EMETOGENIC CHEMOTHERAPY
NDA 205834	HARVONI	LEDIPASVIR AND SOFOSBUVIR	GILEAD SCIENCES INC	P	10/10/2014	FOR THE TREATMENT OF CHRONIC HEPATITIS C, GENOTYPE 1 INFECTION
NDA 022535	ESBRIET	PIRFENIDONE	INTERMUNE INC	P,O	10/15/2014	FOR THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS (IPF)
NDA 205832	OFEV	NINTEDANIB	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	P,O	10/15/2014	FOR THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS (IPF)
NDA 206307	XTORO	FINAFOXACIN	ALCON RESEARCH LTD	P	12/17/2014	FOR TREATMENT OF ACUTE OTITIS EXTERNA (AOE) CAUSED BY SUSCEPTIBLE STRAINS OF PSEUDOMONAS AERUGINOSA AND STAPHYLOCOCCUS AUREUS
NDA 206162	LYNPARZA	OLAPARIB	ASTRAZENECA PHARMACEUTICALS LP	P,O	12/19/2014	SUSPECTED DELETERIOUS GERMLINE BRCA MUTATED ADVANCED OVARIAN CANCER WHO HAVE BEEN TREATED WITH THREE OR MORE PRIOR LINES OF CHEMOTHERAPY
NDA 206426	RAPIVAB	PERAMIVIR	BIOCRIST PHARMACEUTICALS INC	S	12/19/2014	FOR INTRAVENOUS USE, FOR THE TREATMENT OF ACUTE UNCOMPLICATED INFLUENZA IN PATIENTS 18 YEARS AND OLDER WHO HAVE BEEN SYMPTOMATIC FOR NO MORE THAN 2 DAYS
NDA 206619	VIEKIRA PAK	OMBITASVIR, PARITAPREVIR, RITONAVIR, DASABUVIR	ABBVIE INC	P	12/19/2014	FOR THE TREATMENT OF PATIENTS WITH GENOTYPE 1 CHRONIC HEPATITIS C VIRUS (HCV) INFECTION INCLUDING THOSE WITH COMPENSATED CIRRHOSIS
NDA 206829	ZERBAXA	CEFTOLOZANE/TAZOBACTAM	CUBIST PHARMACEUTICALS INC	P	12/19/2014	FOR THE TREATMENT OF COMPLICATED URINARY TRACT INFECTIONS (UTI) AND COMPLICATED INTRA-ABDOMINAL INFECTIONS (IAI)

Original Biologic License Application (BLA) Approvals:

BLA NUMBER	PROPRIETARY NAME	PROPER NAME	APPLICANT	REVIEW CLASSIFICATION	APPROVAL DATE	INDICATION
BLA 125460/0.0	VIMIZIM	ELOSULFASE ALFA	BIOMARIN PHARMACEUTICAL INC.	P,O	2/14/2014	INDICATED FOR PATIENTS WITH MUCOPOLYSACCHARIDOSIS TYPE IVA (MPS IVA; MORQUIO A SYNDROME). □
BLA 125390/0.0	MYALEPT	METRELEPTIN	AMYLIN PHARMACEUTICALS, LLC	P,O	2/24/2014	INDICATED AS AN ADJUNCT TO DIET AS REPLACEMENT THERAPY TO TREAT THE COMPLICATIONS OF LEPTIN DEFICIENCY IN PATIENTS WITH CONGENITAL OR ACQUIRED GENERALIZED LIPODYSTROPHY
BLA 125431/0.0	TANZEUM	ALBIGLUTIDE	GLAXOSMITHKLINE LLC	S	4/15/2014	INDICATED AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS.
BLA 125477/0.0	CYRAMZA	RAMUCIRUMAB	ELI LILLY AND COMPANY	P,O	4/21/2014	INDICATED FOR THE TREATMENT OF ADVANCED GASTRIC CANCER OR GASTRO-ESOPHAGEAL JUNCTION ADENOCARCINOMA, AS A SINGLE-AGENT AFTER PRIOR FLUOROPYRIMIDINE-OR PLATINUM-CONTAINING THERAPY
BLA 125496/0.0	SYLVANT	SILTUXIMAB	JANSSEN BIOTECH, INC.	P,O	4/23/2014	INDICATED FOR THE TREATMENT OF PATIENTS WITH MULTICENTRIC CASTLEMAN'S DISEASE (MCD) WHO ARE HUMAN IMMUNODEFICIENCY VIRUS (HIV) NEGATIVE AND HUMAN HERPESVIRUS-8 (HHV-8) NEGATIVE
BLA 125476/0.0	ENTYVIO	VEDOLIZUMAB	TAKEDA PHARMACEUTICALS U.S.A., INC.	P	5/20/2014	INDICATED FOR THE TREATMENT OF ADULT PATIENTS WITH MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS WHO HAVE HAD AN INADEQUATE RESPONSE WITH, LOST RESPONSE TO, OR WERE INTOLERANT TO A TUMOR NECROSIS FACTOR (TNF) BLOCKER OR IMMUNOMODULATOR; OR HAD AN INADEQUATE RESPONSE WITH, WERE INTOLERANT TO, OR DEMONSTRATED DEPENDENCE ON CORTICOSTEROIDS
BLA 125499/0.0	PLEGRIDY	PEGINTERFERON BETA-1A	BIOGEN IDEC INC.	S	8/15/2014	FOR THE TREATMENT OF PATIENTS WITH RELAPSING FORMS OF MULTIPLE SCLEROSIS
BLA 125514/0.0	KEYTRUDA	PEMBROLIZUMAB	MERCK SHARP & DOHME CORP.	P,O	9/4/2014	FOR THE TREATMENT OF PATIENTS WITH UNRESECTABLE OR METASTATIC MELANOMA AND DISEASE PROGRESSION FOLLOWING IPIILIMUMAB AND, IF BRAF V600 MUTATION POSITIVE, A BRAF INHIBITOR
BLA 125469/0.0	TRULICITY	DULAGLUTIDE	ELI LILLY AND COMPANY	S	9/18/2014	AS AN ADJUNCT TO DIET AND EXERCISE TO IMPROVE GLYCEMIC CONTROL IN ADULTS WITH TYPE 2 DIABETES MELLITUS

BLA 125557/0.0	BLINCYTO	BLINATUMOMAB	AMGEN, INC.	P,O	12/3/2014	FOR TREATMENT OF PHILADELPHIA CHROMOSOMENEGATIVE RELAPSED OR REFRACTORY B-CELL PRECURSOR ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)
BLA 125554/0.0	OPDIVO	NIVOLUMAB	BRISTOL-MYERS SQUIBB COMPANY	P,O	12/22/2014	FOR THE TREATMENT OF UNRESECTABLE OR METASTATIC MELANOMA AND DISEASE PROGRESSION FOLLOWING IPILIMUMAB AND, IF BRAF V600 MUTATION POSITIVE, A BRAF INHIBITOR

Review Classification:

P - Priority Review - Significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease.

S - Standard Review - Products that do not qualify for priority review.